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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/872,068	05/31/2001	Brian K. Courtney	MAC1001U	1810

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EXAMINER

KONTOS, LINA R

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 03/26/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/872,068

Applicant(s)

COURTNEY ET AL.

cn

Examiner

Lina Kontos

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-13,15-17,34-38,40-45 and 67 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-13,15-17,34-38,40-45 and 67 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

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\Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1.

Claims 1-3,5,9-12,15,17,34,35,37,38,40,44,45,67 are rejected under 35 U.S.C. 102(e) as being anticipated by Johansson et al.

Johansson et al. teaches a catheter with an expandable occluder, the catheter having a inner shaft extending distally of the occluder and another port also distal to the occluder for the removal of fluid and debris from the vasculature. (Figures 6-10) The balloon is inflated by fluid delivery from lumen (23) that is connected to the wall of the main catheter shaft. A guidewire may be used to assist in the delivery of the catheter to the treatment site. [0134] Fluid from the innermost lumen can be delivered to the vasculature in varying flow rates [0033] The device may be used to deploy a stent to treat the remaining occlusion that could not be removed by fluid dissolution. [0040]

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2.

Claims 6,41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnansson et al. in view of Calderon.

Johnansson et al., as described above, teaches a catheter with an occluder, the catheter having multiple lumens for the delivery of fluid into the vasculature and the removal of debris from the vasculature, but fails to teaches a self-expanding balloon

Calderon teaches a catheter device with an expandable occluder element and means for provding infusion of a fluid and removing debris from a patient's vasculature

It would have been obvious to one skilled in the art at the time of the invention to have the balloon be self expanding to eliminate the need for a separate lumen and port to inflate the balloon.

3.

Claims 7,8,42,43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnansson et al. in view of Booth et al.

Johnansson et al., as described above, teaches a catheter with an occluder, the catheter having multiple lumens for the delivery of fluid into the vasculature and the removal of debris from the vasculature, but fails to disclose a foam-filled occluder.

Booth et al. teaches a balloon (98) that is filled with a foam 999) that is in communication with the inflation means for said balloon.

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It would have been obvious to one skilled in the art at the time of the invention to use foam in the balloon allowing the balloon to expand to its naturally enlarged state upon the release of applied vacuum pressure.

4.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Johnansson et al. in view of Tsugita et al.

Johnansson et al., as described above, teaches a catheter with an occluder, the catheter having multiple lumens for the delivery of fluid into the vasculature and the removal of debris from the vasculature, but fails to disclose a filter.

Tsugita teaches a catheter having a balloon (40), an infusion port distal to the balloon and a filter for trapping the material loosening from the clot.

It would have been obvious to one skilled in the art at the time of the invention to incorporate a filter into the device in order to trap the particles that were loosening from the clot and prevent them from travel elsewhere in the vasculature.

5.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Johnansson et al. in view of Mocoviak et al.

Johnansson et al., as described above, teaches a catheter with an occluder, the catheter having multiple lumens for the delivery of fluid into the vasculature and the removal of debris from the vasculature, but fails to teaches a sealing mechanism at the distal portion of the catheter.

Mocoviak et al. teaches a perfusion shunt apparatus for isolation and perfusion of an area of a patient's cardiovascular system comprising an expandable occluder (110) with embolic

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protection means (108). Catheter has a flexible seal on the distal end of the catheter that flexes to allow the passage of a guidewire while having a fluid-tight seal (column 8, lines 22-26).

It would have been obvious to one skilled in the art at the time of the invention to incorporate the use of a flexible seal at the distal region of the catheter in order to prevent perfusate from passing through the distal opening.

6.

Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Johnasson et al. in view of Booth et al.

Johnasson et al., as described above, teaches a catheter with an occluder, the catheter having multiple lumens for the delivery of fluid into the vasculature and the removal of debris from the vasculature, but fails to teach multiple openings on the distal end of the inner catheter.

Booth et al. teaches a catheter for retrograde perfusion comprising an occluding member, (46), and catheter with multiple infusion ports (48).

It would have been obvious to one skilled in the art at the time of the invention to include multiple infusion ports to allow for a more controlled flow rate of the fluid or

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lina Kontos whose telephone number is (703) 306-4207. The examiner can normally be reached on M-F 8:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703) 308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LRK


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